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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2004D–0549]

Draft Guidance for Industry on Labeling Over-the-Counter Human Drug Products; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Labeling OTC Human Drug Products—Questions and Answers." This guidance is intended to assist manufacturers, packers, and distributors of over-the-counter (OTC) drug products to implement the agency's regulation on standardized content and format requirements for the labeling of OTC drug products. This draft guidance discusses labeling questions that have been frequently asked by manufacturers, packers, and distributors in implementing the new requirements. The labeling examples in this draft guidance show various format and content features and suggest how OTC drug monograph labeling information finalized before the new requirements can be converted to the new format.

DATES: Submit written or electronic comments on the draft guidance for industry by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and

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Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Cazemiro R. Martin or Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Labeling OTC Human Drug Products—Questions and Answers." This is one of several draft guidances the agency is developing to help manufacturers, packers, and distributors implement the regulation establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these draft guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format requirements for the labeling of OTC drug products (21 CFR 201.66). This regulation is intended to standardize labeling for all OTC drug products so consumers can easily read and understand OTC drug product labeling and use these products safely and effectively.

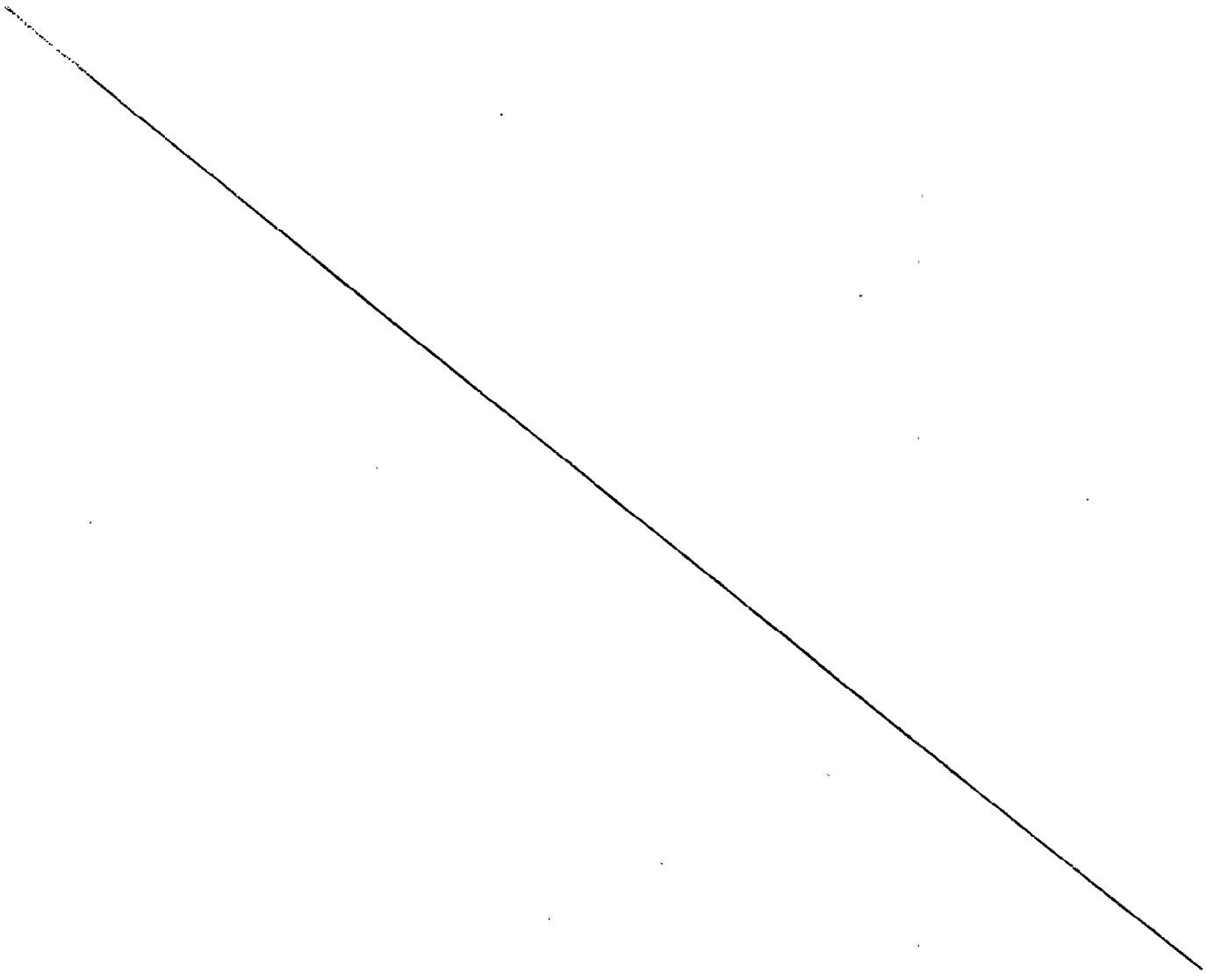
The regulation for this standardized labeling requires manufacturers to present OTC drug labeling information in a prescribed order and format. The standardized format will require revision of all labeling in use before the compliance date of the final rule. The final rule covers all OTC drug and drug-cosmetic products, whether marketed under a new drug marketing application, abbreviated new drug application, or OTC drug monograph (or product not yet the subject of a final OTC drug monograph).

Following issuance of the final rule, the agency received a number of inquires from manufacturers seeking guidance on how to present the labeling information for their OTC drug products using the standardized content and format requirements. This draft guidance discusses those inquiries and provides labeling examples to show various format and content features of the labeling requirements and suggest how OTC drug monograph labeling finalized before the new regulation was issued can be converted to the new format. This draft guidance also discusses how to list inactive ingredients that may or may not be contained in the OTC drug product.

This level I draft guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The draft guidance includes labeling examples that are consistent with the new OTC drug products standardized labeling content and format. The draft guidance represents the agency's current thinking on how OTC drug monograph labeling can be converted to the new OTC "Drug Facts" format labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two copies of any mailed comments except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: December 28, 2004

December 28, 2004.

William K. Hubbard,
Associate Commissioner for Policy and Planning.

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